PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

BAYLISS, GEOFFREY CYRIL
BOULT WADE TENNANT
VERULAM GARDENS
70 GRAY'S INN ROAD
LONDON WC1X 8BT
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	17.11.2006

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
P64961WO00	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB2004/005313	17.12.2004	22.12.2003

Applicant
BIOQUELL UK LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Sloan, Mary Tel. +49 89 2399-2606

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
P64961WO00		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB2004/005313	17.12.2004	22.12.2003

International Patent Classification (IPC) or national classification and IPC
INV. A61L2/20

Applicant
BIOQUELL UK LIMITED et al.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 7 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in Item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05.07.2005	17.11.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Connor, Marco Telephone No. +49 89 2399-8402

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/005313

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
2, 4-15	as originally filed
1, 1a, 1b, 3	received on 05.07.2005 with letter of 04.07.2005
Claims, Numbers	
1-11	received on 05.07.2005 with letter of 04.07.2005
Drawings, Sheets	
1/3-3/3	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/005313

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-11
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-11
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.
PCT/GB2004/005313

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 The present application does not meet the requirements of Article 6 PCT for the following reasons.

1.1 Figures 1 and 5 are exactly the same, the former comprising text references and the latter numerical references. It is not understood, why Figure 1 could not comprise both numerical and text references and delete Figure 5 thus rendered redundant.

1.2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

1.3 According to the requirements of Rule 10.2 PCT, the terminology and the signs shall be consistent throughout the application. This requirement is not met in view of the use of the expressions gas generator and internal aeration referred to as #21 and 40 in Figures 2 and 3, respectively and as 14 and 15 in Figure 5.

1.4 The embodiments not falling within the ambit of present claim 1 should either be deleted or clearly identified as not belonging to the claimed invention (e.g., Figure 2).

1.5 Claim 6 appears to be redundant with present claim 1, which amendments seem to be based on original claim 6.

2 The following documents were cited in the search report:

D1: US-A-5 229 071 (MEO, III ET AL) 20 July 1993 (1993-07-20)
D2: US-A-5 160 700 (ANDERSON ET AL) 3 November 1992 (1992-11-03)
D3: US 2003/086820 A1 (MCDONNELL GERALD E ET AL) 8 May 2003 (2003-05-08)
D4: US-A-3 503 703 (ROBERT L. MCDONALD ET AL) 31 March 1970 (1970-03-31)
D5: WO 03/082355 A (BIOQUELL UK LIMITED; ADAMS, NICHOLAS, MARK, TURNER; WATLING, DAVID) 9 October 2003 (2003-10-09)

3 The subject matter of claim 1 is considered to fulfil the requirements of Article 33 PCT

in terms of novelty, inventive step, and industrial applicability for the following reasons.

3.1 D1 and D4 disclose an enclosure for carrying out an operation under sterile conditions differing from the subject matter of present claim 1 in that inter alia, they comprise no plenum chamber, nor pump for said plenum chamber for delivering air into the plenum chamber and to the main chamber to create a filtered flow of air. D4 may probably be considered as closest prior art as it discloses a multichamber apparatus comprising a flexible sterilization chamber (12) connected to a chamber (70) comprising sterilant in fluid communication with a chamber (60) comprising a fan (58),. Said chamber (60) is in fluid communication

(a) via a filter (64) with an outlet chamber (62) filled with a gas sorbing agent (65) and comprising an outlet (67), and
(b) via a filter (90) with a chamber (87), which connects to the flexible chamber (12).

The apparatus disclosed in D4, however, is based on a different principle than the one called for in present claim 1. Filtered air is introduced into inlet (49), is filtered in (50) and (55), before being introduced into the flexible chamber (12) where it is sucked back into duct (29), through filter (90) into chamber (60) wherein it closes the cycle by passing through chamber (70) where it picks up sterilant vapour and is turned back into flexible chamber (12) through filter (55) and duct (28). After several such cycles, the air is released through filter (64) into chamber (62) filled with gas sorbing agent (65) and released via outlet (67).

In the apparatus called for in present claim 1, air is introduced into and evacuated from the main chamber through the plenum chamber. There is no way the skilled person starting from D4 could arrive at the subject matter of present claim 1 without involving an inventive step (or without hindsight). The subject matter of present claim 1 can therefore be considered as inventive in the sense of Article 33(3) PCT.

Apparatus for Bio-decontamination of Enclosures

This invention relates to apparatus for the bio-decontamination of enclosures and in particular small enclosures.

US-A-5,229,071 discloses a batch method and apparatus for controlled release of gaseous air contaminants into the atmosphere through catalytic oxidation while minimizing both the energy required and the volume of waste gas exhausted into the atmosphere. The device has a recirculating gas stream driven by a recirculation fan which moves gas, normally and naturally present at start-up, through a bed of granular catalyst, in an oxidizer and into contact with the surface of a process-gas heater and back to the recirculation fan. The gaseous contaminants may be drawn into this system using a vacuum pump.

US-A-5,160,700 discloses a sterilizing system including a sealed container for holding a gaseous sterilant under pressure and a first enclosure made at least partially of a gas-permeable material. The container and the articles to be sterilized are disposed in and sealed within the first enclosure, and the container, while in the sealed first enclosure, is manipulated to release gaseous sterilant into the sealed first enclosure. A second enclosure in which the first enclosure is disposed is constructed such that the sterilant released into the first enclosure from the container diffuses through the gas-permeable material of the first enclosure into the second enclosure at a rate capable of establishing sterilizing conditions in the first enclosure during a sterilizing cycle to thereby effect

sterilization of the articles in the first enclosure. A moisture-releasing humidifying device is disposed within the first enclosure for releasing moisture into the first enclosure during the sterilization cycle and a regulating system comprising an exhaust device is operable to exhaust the sterilant gas from the second enclosure to minimize the amount of sterilant gas in the second enclosure, thereby providing for minimized residue sterilant in the surrounding work area.

US-A-2003/0086820 discloses that a surface which carries a material which is infected with prions is cleaned with an alkaline cleaning solution to remove as much proteinaceous material as possible from the surface. The solution contains an alkaline cleaning agent which attacks prions remaining on the surface and which also attacks prions removed from the surface during the cleaning step. After the cleaning step, the surface is exposed to a strong gaseous oxidant, preferably hydrogen peroxide vapor. The hydrogen peroxide or other strong oxidant attacks the prions, particularly the unclumped prion strands, deactivating the prions.

US-A-3,503,703 discloses a sterilizing apparatus having a gas impermeable barrier and a flexible, collapsible gas impermeable bag having an aperture for receiving articles to be sterilized adapted to be mounted in gastight connection with the barrier. The bag is connected to the barrier in a gastight relationship and exhaust means are provided for reducing the internal pressure in the bag and for circulating air in the bag and valving and controls are provided for carrying out a sterilizing cycle in the bag.

Small enclosures are typically up to about $2m^3$ in volume, and include but are not limited to Class II Microbiological Safety Cabinets (MSC). Our International Patent Application PCT/GB03/001386 discloses methods of bio-decontaminating larger enclosures such as rooms or chambers by placing an apparatus to generate the fumigant gas inside the chamber. The technique described works well for rooms and large chambers of a simple nature but is not specifically intended to deal with the problems associated with Class II microbiological safety cabinets and similar enclosures.

The standard technique for bio-decontaminating a Class II MSC is to boil formalin to generate formaldehyde vapour. For this method to be effective substantial amounts of formalin have to be evaporated, the European Standard EN BS 12469 requires 60ml of formalin plus 60ml of water to be evaporated for each cubic metre of enclosure volume. Other authorities use smaller amounts of liquid but all of the methods used generate considerable amounts of condensation within the MSC and also form deposits of paraformaldehyde.

Formalin gassing of an MSC has a number of disadvantages; firstly it leaves a residue of formalin and paraformaldehyde that can only be removed by long periods of aeration; secondly the bio-decontamination process is slow, the normal exposure time being eight hours; thirdly it is difficult to

the process is very fast. Many, if not most, Class II MSCs that are in use recirculate their exhaust air back to the laboratory, and hence a method is required to remove the hydrogen peroxide vapour at the end of the bio-decontamination cycle.

The present invention is a technique to overcome these problems and provide a safe and reliable way to bio-decontaminate small enclosures including MSCs.

This invention provides an enclosure for carrying out an operation under sterile conditions comprising a main chamber containing a first apparatus disposed within the chamber for generating and delivering a sterilant vapour from a supply held within the chamber to be distributed throughout the chamber to sterilise the surfaces, a plenum chamber, a filter separating the plenum chamber from the main chamber, a pump for the plenum chamber for delivering air into the plenum chamber and then through the filter to the main chamber to create a filtered flow of air through the chamber and means to draw gas from the enclosure via an outlet from the plenum chamber to create a flow of sterilant vapour from the main chamber through the filter decontaminating the filter and through the plenum chamber to the outlet to sterilise the plenum chamber before exiting the outlet from the plenum chamber and to maintain pressure in the main and plenum chambers below atmospheric so that any leak paths result in leakage from the atmosphere into the chambers and does not result in release of sterilant vapour to the atmosphere around the enclosure.

In accordance with one embodiment of the invention the means for drawing gas from the enclosure comprise a fan located in a conduit connected to an outlet from the enclosure, the conduit having means to render sterilant reaching the

(100)

CLAIMS

1. An enclosure for carrying out an operation under sterile conditions comprising a main chamber containing a first apparatus disposed within the chamber for generating and delivering a sterilant vapour from a supply held within the chamber to be distributed throughout the chamber to sterilise the surfaces, a plenum chamber, a filter separating the plenum chamber from the main chamber, a pump for the plenum chamber for delivering air into the plenum chamber and then through the filter to the main chamber to create a filtered flow of air through the chamber and means to draw gas from the enclosure via an outlet from the plenum chamber to create a flow of sterilant vapour from the main chamber through the filter decontaminating the filter and through the plenum chamber to the outlet to sterilise the plenum chamber before exiting the outlet from the plenum chamber and to maintain pressure in the main and plenum chambers below atmospheric so that any leak paths result in leakage from the atmosphere into the chambers and does not result in release of sterilant vapour to the atmosphere around the enclosure.

2. An enclosure as claimed in claim 1, wherein the means for drawing gas from the enclosure comprise a fan located in a conduit connected to an outlet from the enclosure, the conduit having means to render sterilant reaching the conduit ineffective to avoid release of sterilant to atmosphere.

3. An enclosure as claimed in claim 2, wherein the means to render the sterilant ineffective are located upstream of the fan in relation to the enclosure.

4. An apparatus as claimed in claim 3, wherein the means to render the sterilant ineffective comprise a catalytic converter for breaking the sterilant down into harmless biproducts which can be exhausted to atmosphere.

5. An enclosure as claimed in claim 3 or claim 4, wherein the conduit has selectively operable valve controlled outlets of larger and smaller capacities, the smaller capacity outlet being open during said period when the enclosure is to be maintained at a predetermined reduced pressure and the larger valve controlled outlet being opened during discharge of the sterilant atmosphere from the enclosure.

6. An enclosure as claimed in any of the preceding claims wherein the enclosure has a main chamber containing said apparatus for producing sterilant vapour and within which the operation to be carried out in the chamber is performed and a plenum chamber separated from the main chamber by a filter, the plenum chamber having a pump for delivering air into the plenum chamber through the filter to the main chamber to create a filtered flow of air through the chamber and the means for drawing gas from the chamber remote from the first apparatus is connected to the plenum chamber.

7. An enclosure as claimed in claim 6, wherein a filter is provided in the outlet from the plenum chamber to the means for drawing gas from the plenum chamber.

8. An enclosure as claimed in any of the preceding claims, wherein the enclosure contains a second apparatus for rendering sterilant in the atmosphere in the chamber ineffective after the sterilisation of the chamber.

9. An enclosure as claimed in claim 8, wherein the means for rendering sterilant ineffective comprises a housing containing a catalytic converter for converting the sterilant into harmless biproducts for disposal and means for circulating the atmosphere of the chamber through the housing to reduce the sterilant concentration in the atmosphere when the sterilisation operation has been performed.

10. An enclosure as claimed in any of the preceding claims, wherein the outlet from the plenum chamber contains an exhaust filter through which air/sterilant vapour is drawn from the chamber.

11. An enclosure as claimed in claim 10, wherein the outlet from the plenum chamber contains two spaced filters through which sterilant vapour is drawn from the plenum chamber.